

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: All Direct Purchaser Actions	Case No. 1:15-cv-07488-CM-RWL
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**PLAINTIFFS' TRIAL BRIEF CONCERNING
THE MEANING OF "LARGE" UNDER *FTC V. ACTAVIS, INC.***

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ARGUMENT

The Court has asked (ECF No. 887) for briefing on the issue of “large in relation to what.” Forest has argued that it should be permitted to offer evidence and argument that its reverse payments to Mylan were not large in relation to Namenda’s sales or profits. Forest says that *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) blesses that argument since the risk of losing brand sales and profits is purportedly a normal settlement concern. Plaintiffs say that, to the contrary, paying amounts greater than the brand’s saved litigation expenses to prevent the risk of competition is the very anticompetitive conduct that the Supreme Court condemns.

This Court asked “what other judges have done on this issue since *Actavis*”? Other courts have repeatedly held that the size of a reverse payment should be measured against (1) the brand company’s avoided patent litigation costs; and/or (2) the amount necessary to induce the generic to drop its patent challenge. The first measure follows from simple economic logic: a rational brand company will not pay its generic competitor more than it would pay its own patent lawyers to continue litigating *unless* the brand were buying more protection from competition that it would expect to obtain by paying its patent lawyers. As Judge Jan E. Dubois explained in a post-*Actavis* decision:

[W]hen bargaining for an early entry date alone, the parties are likely to agree on a date that reasonably approximates each party’s relative strength in the infringement litigation. In contrast, a reverse payment of cash by the brand-name manufacturer to the potential generic manufacturer is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree based solely on the estimated strength of its litigation position.

In re Niaspan Antitrust Litig., 42 F. Supp. 3d 735, 751-52 (E.D. Pa. 2014). *See also King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) (“when the parties’ settlement includes a no-AG [no-authorized generic] agreement, the generic also

presumably agrees to an early entry date that is later than it would have otherwise accepted.”).

The brand’s avoided litigation costs is the *only* quantitative measure of “large” mentioned by the Supreme Court. 570 U.S. at 156, 159.

Actavis also explained that a qualitative analysis of “large” looks at the amount sufficient to “induce the generic to abandon its” patent challenge. *Id.* at 154. Inducing the generic to stop trying to compete, of course, harms competition by definition.

Courts since *Actavis* have, accordingly, repeatedly held that “large in relation to what” means “large in relation to the brand’s saved litigation costs or large enough to induce the generic to drop its patent challenge.” See *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 (1st Cir. 2016) (*Actavis* “emphasizes . . . the size of the reverse payment, particularly as it relates to potential litigation expenses”); *King Drug Co. of Florence*, 791 F.3d at 406 (holding that *Actavis* rejected the argument that brand defendant had a “right to use valuable licensing in such a way as to induce a patent challenger’s delay.”); *In re AndroGel Antitrust Litig. (No. II)*, MDL No. 2084, 2018 WL 2984873, at *9 (N.D. Ga. June 14, 2018) (“Thus, if the settlement payments are shown to be larger than what could reasonably be expected to cover such traditional settlement concerns as future litigation costs or the value of services rendered, the Plaintiffs will have satisfied their burden in showing that the settlements violated the antitrust laws.”) (footnote omitted); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) (“exceeded the estimated cost of litigation”); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 719 (N.D. Ill. 2016) (“large in comparison to the value of the avoided litigation costs.”); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416-17 (E.D. Pa. 2015) (“large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its

patent claim”); *In re Actos End Payor Antitrust Litig.*, No. 13–CV–9244 (RA), 2015 WL 5610752, at *19 (S.D.N.Y. Sept. 22, 2015) (“compared to the payor’s future litigation costs as a measure of scale.”), *aff’d in part and rev’d in part on other grounds*, 848 F.3d 89 (2d Cir. 2017); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14–md–02503–DJC, 2015 WL 5458570, at *7-9 (D. Mass. Sept. 16, 2015) (holding that a payment is “large” where it exceeds “saved litigation costs” and rejecting argument that \$8 million was not “large”); *United Food & Commercial Workers Local 1776 & Participating Emp’rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1072 (N.D. Cal. 2014) (“approximation of the costs of continuing the patent litigation”). *See also* Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 2046d6 at 387-88 (Supp. 2015) (*Actavis* “does not require evidence of a payment of a particular size, but only a payment in excess of *reasonably anticipated litigation costs*.”) (emphasis added); *id.* ¶ 2046d5 (“in comparison with litigation costs”); Aaron S. Edlin, C. Scott Hemphill, Herbert J. Hovenkamp, Carl Shapiro, *Activating Actavis*, 26 ANTITRUST 16, 21 (Fall 2013) (proposing jury instructions emphasizing the significance of avoided litigation costs: “In assessing whether this payment is unreasonably large, you may consider whether the payment is no greater than the patent holder’s anticipated litigation costs that are avoided through settlement.”).

As discussed at the pretrial conference, *Actavis* summarized the critical antitrust issue in a reverse payment case: “Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.” 570 U.S. at 158. As Judge Thrash put it: “The size of the payment is merely the Supreme Court’s proxy for

reaching the ultimate question: whether the agreement was entered into for the purpose of avoiding the risk of competition. If a settlement was agreed to for that purpose, it is ‘large and unjustified.’” *In re AndroGel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *11.

Forest suggests, however, that its “desire to maintain and to share” its monopoly profits with Mylan is a *defense* – that is, Forest wants to persuade the jury that its reverse payment to Mylan, though even more than Mylan’s own expected profits on its generic, was not “large” and therefore not unlawful, because the payment was small in comparison to the billion-dollar annual sales of Namenda. As noted by Judge Thrash, the question of whether a payment is “large” is not an end unto itself – it is a way to answer the “ultimate question: whether the agreement was entered into for the purpose of avoiding the risk of competition.” It would be error to allow Forest to try to convince the jury that, even though it paid a portion of its monopoly profits to Mylan to protect those same profits from the risk of competition, its payment was small in comparison to those same monopoly profits and so lawful. What the Supreme Court condemned cannot be a defense. Thus, Judge Orrick excluded such evidence and argument in *Lidoderm*.

There, plaintiffs filed a motion *in limine* seeking to preclude defense evidence and argument at trial that the reverse payments were not large compared to the brand companies’ profits. *See In re Lidoderm Antitrust Litig.*, No. 14-md-02521, Pls.’ Mots. *in Limine*, at 21 (N.D. Cal. Nov. 6, 2017) (ECF No. 998-44). Judge Orrick agreed, and granted the motion. He reasoned:

Actavis instructs that “large” is hinged to anticipated saved litigation costs and its independence from payments for other services. The Court’s analysis in *Actavis*, in rejecting the scope of the patent [test], teaches away from considering at the very least the defendant’s profits from the drug at issue.

In re Lidoderm Antitrust Litig., 2018 WL 7814761, at *7 (N.D. Cal. Feb. 7, 2018).

As another example, Judge Goldberg in *In re Modafinil Antitrust Litigation* charged the jury as follows:

Whether a payment is large depends on the specific facts and circumstances of this case. Generally, a reverse payment is large if it meets two criteria.

First, you must ask whether the payment exceeds the patent holder's — here, Cephalon's — anticipated future litigation costs.

Second, you must consider whether the payment was significant enough to induce a generic challenger — here, Ranbaxy — to abandon its patent claim and stay off the market. One factor you may consider in assessing whether the payment was significant enough to induce Ranbaxy to stay off the market, is whether the payment comes close to or exceeds the expected profit to be earned by Ranbaxy if it had prevailed in the patent litigation.

Declaration of Bruce Gerstein (“Gerstein Decl.”), Ex. 1, *Apotex, Inc. v. Ranbaxy Labs. Ltd.*, No. 06-2768, Final Jury Instructions, at 15 (E.D. Pa. July 6, 2017) (ECF No. 1259) (citing *King Drug Co. of Florence*, 88 F. Supp. 3d at 416-18 (rejecting “Defendants’ argument that the brand manufacturer’s expected monopoly profits constitutes the appropriate benchmark” for a large reverse payment)).

In prior Motion *in Limine* briefing, Forest claimed that Judge Goldberg “permitted the parties to offer evidence of the patent’s revenues.” Forest’s Opp. to Pls.’ Mot. *in Limine* No. 8 (ECF No. 847 at 6). That was misleading at best. Judge Goldberg never issued any ruling “permitting” such argument. Rather, his practice was to put the burden on the parties to object to improper argument. During opening statements, defense counsel compared the reverse payment there to “the worldwide pharmaceutical market” which “at the time of this settlement was 600 billion,” and to the brand’s “5.7 billion in Provigil sales[.]” Gerstein Decl. Ex. 2, *Apotex, Inc. v. Ranbaxy Labs. Ltd.*, Trial Tr., Jun. 14, 2017 at 113:13-14, 114:6-7. Judge Goldberg later noted that “there was a lot of improper arguments in openings” about payment size, but insisted that

objections must be made “in the moment.” Gerstein Decl. Ex. 3, *Apotex, Inc. v. Ranbaxy Labs. Ltd.*, Trial Tr., Jun. 26, 2017 at 26:16-18. “But no one objected, and now we have this problem everyone is concerned about. So object. It’s going to make the trial longer, but I can’t rule in space here. Let’s rule – hear a question, if you think it is too far, object, and I will rule.” *Id.* at 27:2-6. Plaintiffs there never objected to any further evidence or closing argument concerning comparisons to brand sales (the parties announced a settlement right after closings), and so Judge Goldberg never ruled on the impropriety of such arguments. But his instructions to the jury mentioned only two measures: (1) the brand’s saved litigation costs; and (2) the amount sufficient to induce the generic to end its patent challenge.

Because a brand company’s patent-protected profits far exceed a cheaper generic’s profits, a brand company need not pay a “large” portion of its profits to induce anticompetitive delay. On average, for example, generic prices are 85% below brand prices within a year (*see* PX-1065 at 8) (under advisement) and generic Namenda IR prices were lower still (more than 94% below brand prices within the first month, *see* PX-1643 (in evidence)). This vast disparity between brand and generic prices is precisely what led to the rise of reverse payments in the 1990s in the first place – brand companies wanted to protect their patent-protected profits and could easily share some of those profits to induce generic competitors to drop their efforts to compete. *See, e.g., In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 241 (D. Conn. 2015) (“Of course, it will generally be in the interest of both patent-holder and patent-challenger to share the monopoly profits rather than compete.”).

The brand-generic profit disparity is so large that brand companies can pay generics even more than generics could earn if they actually competed and sold their generic – a payment so large that it may “provide strong evidence that the patentee seeks to induce the generic

challenger to abandon its claims with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Actavis*, 570 U.S. at 154.

We have precisely such “strong evidence” here. By Forest’s own admission, Forest sought to induce Mylan to abandon its challenge to Forest’s patent by arguing that its “[c]urrent settlement offer provides more value than Mylan’s forecasted profits for generic memantine.” PX-130 (in evidence); PX-137 (in evidence). To allow Forest to argue that its reverse payment is *not* large even if it admittedly exceeds the amount the Supreme Court recognized as an extreme case for a large payment invites jury confusion and is precisely the kind of indirection Rule 403 was designed to prevent.

The Supreme Court in *Actavis* rejected the very argument Forest made in the pretrial conference that led to this supplemental briefing: Like Forest, the Eleventh Circuit had reasoned, “[w]hen hundreds of millions of dollars of lost profits are at stake, ‘even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement.’” *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1313 (11th Cir. 2012) (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F. 3d 1294, 1310 (11th Cir. 2003)), *rev’d*, *FTC v. Actavis*, 570 U.S. 136 (2013). The Supreme Court, however, *rejected* the very reasoning Forest urged at the pretrial conference that business or litigation realities — like the risk of sales and profits lost to competition in the event of a patent decision unfavorable to Forest — should inform whether a reverse payment is large or not and thus lawful or not. *Actavis*, 570 U.S. at 157-58 (“be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, *that consequence constitutes the relevant anticompetitive harm*”) (emphasis added).

Given these clear statements, it would be very confusing to permit Forest's counsel to ask the jury to evaluate the size of Forest's reverse payments against Namenda revenues or profits.

This is doubly so because the jury certainly will not be hearing from Forest's experts that Namenda's patent-protected revenues are the correct benchmark by which to measure Forest's reverse payment to Mylan. Forest's economist, Dr. Fowdur, exclusively refers to Forest's avoided litigation costs as the comparator by which to measure Forest's reverse payment to Mylan. *See* Expert Report of Lona Fowdur, Ph.D. (Oct. 9, 2017) (ECF No. 696, Ex. F) at ¶ 9 (“payments from Forest to Mylan under the patent settlement were below *Forest's avoided litigation costs* and therefore do not support the conclusion that they delayed Mylan's entry”) (emphasis added). *See also id.* at ¶ 36 (comparison to “avoided litigation costs”); ¶ 37 (same); ¶ 39 (same); ¶ 42 (same); ¶ 61 (same); ¶ 85 (same). Dr. Fowdur echoed her use of this benchmark in her deposition. *See* Gerstein Decl. Ex. 4, Dep. of Lona Fowdur, Ph.D. at 92:11-23 (Oct. 20, 2017) (“But you approach the question from the perspective of an economist. You ask the question of whether the size of the reverse payment was large enough to base an inference of delay on. And one benchmark that is ubiquitous in the literature that economists have put forth is litigation costs, avoided litigation costs. So, to the extent that you find a payment that is below avoided litigation costs, one would have no economic basis to conclude that delay has been incentivized.”). Nowhere in her report or deposition does Dr. Fowdur so much as imply what Forest's counsel now urge: that a reverse payment should be compared to the brand's patent-protected profits it risks losing.

Forest previously also cited to *Barba v. Shire US, Inc.*, No. 13-cv-21158, 2016 WL 3964606 (S.D. Fla. Jan. 19, 2016), and a text order in *In re Solodyn (Minocycline Hydrochloride Antitrust Litig.*, No. 14-md-2503 (D. Mass. Mar. 8, 2018). *See* ECF No. 847 at 3. In *Barba*,

Magistrate Judge Goodman issued a report and recommendation on plaintiff's *Daubert* motion to exclude a defense expert, Dr. Bell, on the grounds that the expert failed to consider saved litigation costs in analyzing the alleged reverse payment in that case. Magistrate Goodman viewed the issue of "largeness" as related and linked to, but not identical to, the "*overall* issue of whether the payment is anticompetitive." 2016 WL 3964606, at *4 (emphasis in original). While the Magistrate recommended that Dr. Bell's testimony on "largeness" not be excluded for failure to consider saved litigation costs, the Magistrate expressly noted that the exact same failure to consider saved litigation costs "could, of course, be a *fatal flaw* in his overall opinion on whether the payment was anticompetitive, but Plaintiffs never raised *that* challenge. . . and so the Court cannot rule on it." *Id.* at *5 (first emphasis added). Unlike Dr. Bell, Forest's expert, Dr. Fowdur, has compared Forest's payment only to saved litigation costs.

In *Solodyn*, defendants argued that comparing the reverse payment to brand sales "first and foremost ...go[es] to the strength of the patent." Gerstein Decl. Ex. 5, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503, Tr. of Final Pretrial Conference, Day 2, Mar. 7, 2018 at 2-9:20-22. That is not an argument that Forest's expert, Dr. Fowdur, has offered, and it is not available to Forest, as we discuss below.

* * *

There is another reason that Forest should be prevented from adducing evidence or making argument encouraging the jury to gauge the size of its reverse payment to Mylan as against its patent-protected Namenda profits. The Court alluded to the reason in the Order requesting this briefing: Forest elected not to waive privilege and instead abandoned various assertions at trial:

Forest is bound by its Disclosure pursuant to Magistrate Judge Francis' May 19, 2017 Order. * * * Forest may not offer any

evidence about its subjective beliefs to rebut any of the following DPP arguments: that its position in the patent cases was weak; that any alleged payment to the generic competitors was large[.] * * * Since Forest affirmatively stated to Magistrate Judge Francis that it would not offer evidence that its position in the patent cases was not weak, it stands to reason that it cannot offer evidence about its subjective belief that its position in the patent cases was strong.

Order Disposing of Mots. *in Limine*, at 12 (citations omitted) (ECF No. 859). Yet the only conceivable relevance of the Namenda reverse-payment's size in relation to Forest's patent-protected profits is to allow Forest to show exactly what it is not permitted to show at trial: that it purportedly had confidence in the '703 patent. *See Actavis*, 570 U.S. at 157 ("An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival."). As Judge Underhill in *Aggrenox* explained:

Large reverse payments that are not particularly large in relation to the value of the patent *may show confidence in the patent*, but if they represent payment to avoid the risk of invalidation, then they still run afoul of *Actavis*.

94 F. Supp. 3d at 243 (emphasis altered). But Forest is not permitted to offer evidence or argument that it was allegedly confident in the strength of the '703 patent. Accordingly, the sole purpose for which Forest could conceivably offer evidence or argument that its reverse payment to Mylan was not particularly large in relation to Namenda profits is not a permissible purpose in this case.

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CERTIFICATE OF SERVICE

I hereby certify that on October 18, 2019, I caused the above to be filed electronically by the CM/ECF system.

Respectfully submitted,

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